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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,189

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EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

04/16/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/764,189	Applicant(s) DESAI, JAWAHAR M.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 4, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>February 4, 2008; August 6, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on February 4, 2008.
2. In the reply, the applicant amended claims 1, 4, 8-11 and 15-17. Claims 1-17 are pending in the application.
3. The previous objection to the oath/declaration is withdrawn.
4. The amendment to the specification is acknowledged and the amendment to claim 1 is sufficient to withdraw the previous 112, 2nd paragraph rejection.
5. The terminal disclaimer filed February 4, 2008 is sufficient to obviate the nonstatutory obviousness-type double patenting rejection of claims 1-17 of this application.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on February 4, 2008 and August 6, 2007 are in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDSs are being considered by the Examiner.

Specification

7. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly

state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1, 5 and 7-8 are rejected under 35 U.S.C. 103(a) as being anticipated by Kolin (US 3,734,083).** Kolin '083 discloses:

A tubular member 16 with wing members 20, 22 formed by longitudinally extending slits 19, and tubular member having a distal opening 18.

If means plus function language (112, 6th paragraph) is intended in amended claims 1 and 11 it is improper because there is no structural language in the specification to read into this claim. Thus, the examiner is interpreting the plunger 38 of

Kolin to be the means for resisting the discharge of fluid from the passageway out through the distal opening C4 L33-37 and a valve in the form of a plunger which engages at the distal opening of the catheter. The thermosetting plastic provides the means to bias the wings in their expanded state.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 2-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin '083 in view of Kanesaka (US 5,381,790).** Kolin '083 shows as discussed above but does not directly show a guidewire sized to have the valve seal about the guidewire. Kanesaka, in the analogous art, teaches a guidewire A16. Guidewires members are conventional for aiding in accessing branch arteries as was well known in the art. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083 with the guidewire as taught by Kanesaka to position the Kolin device in the branch arteries. Further, to have used a large diameter guidewire to have valve member opening 42 to be occluded would be obvious to prevent the flow of blood out of the patient during insertion.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin.

Kolin shows as discussed above but does not directly show the valve means comprising a plurality of resilient flaps which flex when exposed to the force of fluid pressure. This limitation describes a slit valve or a duck-bill type valve which are both well known in the art and therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin with the resilient flap valve for controlling the passage of fluid from the distal end of the tubular member.

13. Claims 6, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin '083 in view of Kolin (US 3,757,773). Kolin '083 shows as discussed above but does not directly show an external tube that compresses the wings of the tube. Kolin '773, in the analogous art, teaches that guide tubes for positioning and collapsing flow meter catheters were well known in the art, see background. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083 with the guide tube as taught by Kolin '773, in other words, use the guide tube as in Kolin '773 for inserting the catheter of Kolin '083 in order to insert the catheter into the appropriate blood vessel.

14. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin ('083) in view of Burton et al. (US 5,588,965) ("Burton").

Kolin '083 shows as discussed above but does not directly show the means for resisting comprising at least one protuberance on the wall within the passageway or a

plurality of spaced, annular ribs. Burton, in the analogous art, teaches a fluid resistor 48 which can be of a type well known in the art which is located with the passageway.

Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083 with the resistor on the wall of the passageway as taught by Burton for controlling the rate of passage of fluid.

15. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin '083 in view of Kolin '773 as applied to claim 11 above and further in view of Kanesaka (US 5,381,790). The combination of Kolin '083 and Kolin '773 shows as discussed above but does not directly show a guidewire sized to have the valve seal about the guidewire. Kanesaka, in the analogous art, teaches a guidewire A16. Guidewires members are conventional for aiding in accessing branch arteries as was well known in the art. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083/Kolin '773 with the guidewire as taught by Kanesaka to position the Kolin device in the branch arteries. Further, to have used a large diameter guidewire to have valve member opening 42 to be occluded would be obvious to prevent the flow of blood out of the patient during insertion.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kolin '083 in view of Kolin '773 as applied to claim 11 above.

The combination of Kolin '083 and Kolin '773 shows as discussed above but does not directly show the valve means comprising a plurality of resilient flaps which

flex when exposed to the force of fluid pressure. This limitation describes a slit valve or a duck-bill type valve which are both well known in the art and therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083/Kolin '773 with the resilient flap valve for controlling the passage of fluid from the distal end of the tubular member.

17. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Kolin '083 in view of Kolin '773 as applied to claim 11 above and further in view of Burton.

The combination of Kolin '083 and Kolin '773 shows as discussed above but does not directly show the means for resisting comprising at least one protuberance on the wall within the passageway or a plurality of spaced, annular ribs. Burton, in the analogous art, teaches a fluid resistor 48 which can be of a type well known in the art which is located with the passageway. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Kolin '083/Kolin '773 with the resistor on the wall of the passageway as taught by Burton for controlling the rate of passage of fluid.

Response to Arguments

18. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767